

Test Report

(Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: YDNA-1492-04

No: 20R000919

Issue Date: 2020-05-27

Applicant: NANNING TECBOD BIOLOGICAL TECHNOLOGY CO.,LTD

Address: ROOM 601 FLOOR 6 , B2 BUILDING, NO 19 GUOKAI DADAO, NANNING, GUANGXI, CHINA

Information confirmed by applicant:

Clean air suits

Quantity: eighteen pieces

Standard Adopted:

EN 13795-2:2019 <Surgical clothing and drapes- Requirements and test methods. Part 2 : Clean air suits>

Date Received/Date Test Started: 2020-05-08

Conclusion:

Bursting strength(dry state)[Material]	M
Breaking strength(dry state)[Material]	M
Cleanliness-microorganism[Material]	M
The resistance to dry microbial penetration[Material]	M
Lint and other particles generation in the dry state[Material]	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:

All the tested items are tested under the standard condition (except for indication).

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The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By:

ZiShan Guo

ZiShan Guo Senior Engineer



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Bursting strength (dry state) [Material]

Test Method: EN ISO 13938-1:1999

Test principle:

A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

Test equipment:

Bursting tester

The environmental conditions of the laboratory and test condition:

Pretreatment: Condition the test specimens at 20.1 °C air at 65.3% RH for 24 h

Test area: 10cm²



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Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	1.38×10^3	≥ 40 (Standard performance) EN 13795-2:2019	Pass
2	1.18×10^3		
3	1.34×10^3		
4	1.25×10^3		
5	1.35×10^3		



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Breaking strength (dry state) [Material]

Test Method: EN 29073-3:1992

Test principle:

Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension.
Determination of values for breaking strength and elongation from the recorded force-elongation curve.

Test equipment:

Tensile testing machine

The environmental conditions of the laboratory and test condition:

Pretreatment: Condition the test specimens at 20.1 °C air at 64.9% RH for 24 h

The distance between the clamps: 200 mm

Rate: 100 mm/min



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Results:

Sample	Length (N)	Width (N)	Requirement (N)	Conclusion
1	1309.7	690.5	≥20	Pass
2	1311.1	704.2	(Standard performance)	
3	1290.4	691.8		
4	1274.2	687.5		
5	1291.8	693.6	EN 13795-2:2019	



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Cleanliness-microorganism[Material]

Test Method: EN ISO 11737-1:2018

Test principle:

Take the required samples from the original packaging. Under sterile condition a sample of 100 cm² was cut and placed in a sterile bottle containing 300 ml of BPW. The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for nonselective aerobic bacteria. Another 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a Sa AGAR plate for total number of yeast and molds. Another 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on blood Agar plate for total number of anaerobic bacteria. Non-selective aerobic bacteria were cultured at 30 °C for 3 days and yeast and molds at 25 °C for 7 days and anaerobic bacteria at 30 °C for 3 days. The total bioburden is expressed by addition of three culture plates counts. Five parallel samples are tested.

Test equipment:

Constant temperature incubator

Electronic balance

Pressure steam sterilizer

Biosafety cabinet

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5 °C, Relative humidity: 56.0%

Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

Culture temperature: Bacteria 30 °C, Fungi 25 °C; Culture time: Bacteria 3 days, Fungi 7 days.



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Results:

Sample	total plate count (CFU/100cm ²)	Requirement (CFU/100cm ²)	Conclusion
1	23	≤100 (Standard performance) EN 13795-2:2019	Pass
2	25		
3	33		
4	22		
5	28		



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The resistance to dry microbial penetration[Material]

Test Method: EN ISO 22612:2005

Test principle:

The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with *Bacillus subtilis* is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

Test equipment:

Resistance to dry microbial penetration test

Incubator

Electronic balance

Autoclave

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5°C, Relative humidity: 56.0%

Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.

Dimensions of the test specimens: 200mm×200mm

Sample: 12 pieces

Vibration frequency: 20800 times/min; Vibration time: 30 min.

Test bacteria: The fourth generation of spores of *Bacillus subtilis* ATCC 9372

Concentration of bacterium: 1.8×10^8 CFU/g



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Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	57	≤ 100 (Standard performance) EN 13795-2:2019	Pass
2	69		
3	47		
4	53		
5	33		
6	42		
7	39		
8	47		
9	56		
10	70		



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Lint and other particles generation in the dry state[Material]

Test Method: EN ISO 9073-10:2004

Test principle:

This procedure describes a modified Gelbo Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm .

Test equipment:

Gelbo Flex tester with particle counter

The environmental conditions of the laboratory:

Test environment temperature: 20.0°C, Relative humidity: 65.1%



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Size of particles counted (μm)	Sample		Measured value Coefficient of linting \log_{10}	Requirement Coefficient of linting \log_{10}	Conclusion
3~25	A: Face	1	1.1	≤ 4.0 (Standard performance) EN 13795-2:2019	Pass
		2	1.3		
		3	1.2		
		4	1.2		
		5	1.3		
	B: Face	1	1.0		
		2	1.1		
		3	1.2		
		4	1.2		
		5	1.3		



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——End of Report——